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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/087,905

03/05/2002

Robert L. Campbell

41551

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05/26/2005

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EXAMINER

DEJONG, ERIC S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/087,905

Applicant(s)

CAMPBELL ET AL.

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004 and 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16, 17, 31-40, 55, 56, 59-73, 113-118, 120-122, 124-126, 128 and 129 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17, 31-40, 55, 56, 59-73 and 113-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 120-122, 124-126, 128 and 129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **ACKNOWLEDGMENTS**

Applicants' arguments, filed on 08/20/2004 and 12/30/2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The amended set of claims, filed on 08/20/2004, replace all previous versions of the claims. Claims 1-15, 18-30, 41-54, 5, 74-112, 119, 123, and 127 have been canceled. Claims 16, 17, 31-40, 55, 56, 59-73 and 113-118 are withdrawn from consideration. Claims 128 and 129 are newly added. Claims 120-122, 124-126, 128, and 129 are currently under examination.

### **Sequence Listing**

The applicants' submission of a substitute sequence listing on 30 December 2004 is considered to be a request for substituting the newly filed sequence listing for the previous sequence listing in the specification. In the future applicants are to specifically request entry of newly filed sequence listings into the specification.

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**Withdrawal of Non-Statutory Rejection Under 35 U.S.C. § 101**

Applicants arguments directed toward statutory nature of the claimed subject matter are found convincing, and therefore the rejections on the basis of non-statutory subject matter are hereby withdrawn.

**Withdrawal of Vague and Indefiniteness Rejection Under 35 U.S.C. § 112**

Applicants arguments and amendments to the instant claims directed toward vague and indefiniteness of claim terms are found convincing and, therefore, the previously presented rejections on the basis of vagueness and indefiniteness of terms used in the claims are hereby withdrawn.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 120-122, 124-126, 128 and 129 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by O'Shea et al. This rejection is necessitated by amendments made to the instant claims.

(Claim 128): O'Shea et al. disclose a semiautomatic image analysis method to characterize the morphology of dimorphic yeast undergoing alcoholic fermentation of cheese whey permeate. In addition to qualitative characterization, the method permits measurement of geometric properties of individual or clusters of cells in culture. See O'Shea et al., page 679, Abstract and column 1, line 1 through column 2, line 13. O'Shea et al. disclose that *Kluyveromyces marxianus* var. *marxianus* NRRLy2415 was

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cultured in bioreactors using liquid culture media and can be applied to investigation process variables influencing morphology including shear stress, type of inoculum, medium constituents, pH, and dissolved oxygen concentration (means for constructing a first test library containing a plurality of first culture media, each said first culture media containing a respective first test compound). See O'Shea et al., page 679, column 1, lines 1-20 and page 680, column 1, line 30 through column 2, line 3. O'Shea et al. further disclose that biomass concentrations were estimated from samples of broth taken from cultured growths and dried to obtain a biomass dry cell weight, both lactose and ethanol concentrations from growth media were determined using the dinitrosalicylic acid method (pertaining to lactose) and a Carla Erba HRGC S300 Mega Series gas chromatograph with flame ionization detection, and measurement of morphological parameters of cultured cells were made using a Lecia Q500MC image processing and analysis system linked to an Olympus BX40 brightfield microscope (pertaining to ethanol) (means for determining a relationship between a measured indicia of a property of said plurality of first culture media containing and at least one parameter of said first test compounds). See O'Shea et al. , page 680, lines 4-28. O'Shea et al. further disclose the employment of an algorithm for morphological classification of cell displays in cultured media relying on automated image analysis (means for identifying a second test library containing a plurality of second culture media based on said determined relationship). See O'Shea et al., Figure 2, Image Analysis page 681, line 6 through 685, column 1, line 26. The disclosed algorithm allows for the calculation of properties present in the cell population and is taught as

essential to the successful characterization of effects on cell morphology. Further, O'Shea et al specifically teach that the disclosed system and algorithm is to be used to study the effects of cell morphology from culture media broths and in continuous cell culture conditions examining the effect of dilatation rate (said plurality of second culture media containing a plurality of second test compounds having an estimated indicia which meets a test requirement relating to the measured indicia). See O'Shea et al., page 689, column 1, line 39 through column 2, line 8.

(Claim 120): O'Shea et al. disclose in Figure 5 growth profiles that correlate the levels of lactose and ethanol in cultured media culture media taken over several time points and reads on the claimed determining a relationship in the form of  $\hat{y}_i=f(x_{ij})$ .

(Claim 121): O'Shea et al teach that biomass concentration were estimated by filtering 50-100 mL samples of broth, which reads on the claimed estimated indicia of the property of a plurality of culture media. See O'Shea et al., page 680, column 2, lines 4-19. As disclosed above, the performance of disclosed system and algorithm is to be used to study the effects of cell morphology from culture media broths reads on the claimed plurality of second cultured media which contains a respective tests compound.

(Claim 122): Under a reasonably broad interpretation, the different and distinct cell morphologies that come about in the test cultures reads on the claimed culture medium containing a second test compound that is not within the plurality of first test compounds. As such not the algorithm disclosed O'Shea et al. permits the segregation of cells on the basis of 6 distinct morphologies using the disclosed automated image analysis. Further, O'Shea et al. disclose that "there is an obvious element of overlap in

the categories chosen to describe the cell population. There is no sharp cutoff point between a "long" elongated yeast cell and a "short" filament, for instance. However, it is felt that the separation of the cells studied into six distinct categories facilitates a good insight into the nature of the dynamic growth of a population containing dimorphic cells." See O'Shea et al., page 689, column 1, lines 39-57. Under a reasonable broad interpretation, this disclosure reads on the claimed means for determining a distance function  $d(x_1, x_2) < \text{or} = d_{\text{cutoff}}$  between a first value of a parameter, wherein the parameters are considered to be distinct types of cell morphology and the cutoff is considered a particular type of cell morphology.

(Claims 124-126 and 129): The disclosed systems and algorithm require the use of a bioreactor, a Carla Erba HRGC S300 Mega Series gas chromatograph, a Lecia Q500MC image processing and analysis system linked to an Olympus BX40 brightfield microscope, and the disclosed computerized algorithm that reasonably read on the claimed computer program product readable by a machine and tangibly embodying a program of instructions executable by the machine to perform the above disclosed procedures.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDJ

*EDJ*

*John S. Brusca 22 May 2005*  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER